UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,332	02/16/2001	Gregory Plowman	038602-1083	2179

7590 12/03/2003

Beth A. Burrous
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,332	PLOWMAN ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18 and 21-31* is/are pending in the application.

4a) Of the above claim(s) *17,18 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17-18, drawn to antibodies which specifically bind AUR1-2 polypeptides and hybridomas which produce said antibodies, classified in class 435, subclass 326.

II. Claims 21-25 and 29-31, drawn to methods of treating a disease in a patient utilizing modulators of AUR 1-2 polypeptides, classified in class 514, subclass 12.

III. Claim 28, drawn to antisense oligonucleotides, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

The antibodies of Group I and the DNA of Group III are patentably distinct because each invention is directed to a product of unrelated chemical structure and function.

The method of Group II is unrelated to any of the inventions of Groups I and III. This is because said products are neither made nor used by said method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Todd Spalding on 11/06/2003 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-25 and 29-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-18 and 28 are withdrawn from further

consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claims 21-25 and 29-31 are under examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is a method of use of modulators of AUR1-2 polypeptides. However, claims 24 and 31 which depend from base claim 21 are directed to antisense (DNA) products as modulators. It is not clear how antisense (DNA) can modulate the activity of AUR 1-2 polypeptides.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is directed to the use of AUR 1-2 polypeptide modulators in treatment of patients having diseases related to AUR1-2 over/under expression, which totally lack enablement for the following reasons: (1) the structural definition of AUR1-2 polypeptides is too broad, (2) the diseases suitable for treatment not identified 3) No examples or information (experimental data) in support of claimed method is provided and (4) the nature of AUR1-2 activity (and therefore the structure of AUR modulators) not identified (see below for detailed explanation).

The criteria for undue experimentation, summarized *in re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

Applicant is respectfully requested to look at his/her definition of AUR 1-2 polypeptide provided in the specification (see page 5), wherein he/she defines the "AUR1-2 polypeptides" as having at least 25 or more contiguous amino acids of SEQ ID NO:3-4, or a functional derivative thereof. Applicant is well aware that 25 amino acids of SEQ ID NO:3 or 4 is totally incapable of retaining any activity (kinase or otherwise). As for example in the case of kinases 250-300 amino acids correspond to the kinase active

site and any amino acid sequence consisting of less than 250-300 amino acids is not long enough to retain any kinase function. Therefore, due to aforementioned reasons methods of treatment of patients with a substance that modulates the activity of AUR1-2 polypeptides, as defined in the specification, is subject to lack of enablement.

The specification also fails to teach in which specific diseases modulators of AUR 1-2 polypeptides may be useful. In the case of AUR1 the only tumor tissues that display a consistent pattern of AUR-1 under expression relative to normal tissues can be found in colon (see Northern blot analysis table in the specification). In the case of AUR 2 the Northern blot data is very scarce in order to determine the expression pattern of mRNA of said polypeptide relative to control and therefore it is not possible to determine which diseases may be able to be treated with AUR-2 polypeptide modulators. Hence, based on the information provided, the only disease that appears to have any potential of being treated with modulators of AUR1 polypeptide is colon cancer and the claimed method is not enabled for treatment of at least one disease using modulators of at least one AUR1 and AUR2 .

However, even if one restricts the scope of the claimed invention to in vivo treatment of colon cancer using modulators of AUR-1 polypeptides, the specification fails to teach any experiments or examples in which at least one AUR1 modulator is used to treat tumor tissues and wherein due to such treatment tumor growth is increased or decreased. Current state of prior art indicates that without using AUR1-2 modulators in preliminary tissue culture experiments, it is totally impossible to predict which modulators may be effective in vivo, in patients with AUR1-2 associated diseases

and the skilled artisan has to go through the burden of undue experimentation in order to determine which modulators may have a reasonable expectation of success in being utilized in the claimed method.

Applicant is also reminded that in claims 21-24 and 29-31 the nature of AUR1-2 activity is not specified. Thus, it is not even clear whether the modulators structural information provided in the specification is sufficient to provide support for any modulators of AUR 1-2 polypeptides activities other than kinase. The specification merely provides some general structural information about **kinase** modulators which are not even specific to the in vivo treatment of patients having AUR1-2 related diseases.

Therefore due to lack of sufficient teachings and examples about the structure of AUR1-2 polypeptides, the structure of AUR modulators, and the nature of AUR related diseases provided in the specification and due to unpredictability of prior art as to which AUR1 polypeptides modulators may be effective in treatment of patients with AUR1 related diseases one of skill in the art has to go through the burden of undue experimentation in order to screen for modulators that may be successfully used in the claimed method and as such the claims go beyond the scope of the disclosure.

Claims 21-25 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 and its dependent claims 22-25 and 29-31 are directed to a **genera** of AUR 1-2 polypeptides and a **genera** of

modulators of AUR 1-2 activity which have been inadequately described in the specification.

As mentioned above, the term "AUR 1-2 polypeptides" have been defined as any polypeptide consisting of at least 25 amino acids of SEQ ID NO:3-4 and hence is directed to a **genera** of AUR polypeptide many of which are capable of having many activities. The specification does not contain any disclosure of the function of all the fragments of AUR 1-2 polypeptides. The genera of polypeptides that comprise these above AUR polypeptides is a large variable genera with the potentiality of retaining many activities. Therefore, many functionally unrelated fragments are encompassed within the scope of these claims. The specification discloses only a **single species** for each claimed genus (SEQ ID NO:3-4) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

It should be noted that the claimed invention, namely, claims 21-24 and 29-31 are further subject to lack of written description rejection because they utilize a **genera** of AUR 1-2 modulators of variety of activities which have no support in the specification. The specification does not contain any disclosure of the function of all the modulators of AUR 1-2 polypeptides. The genera of modulators that comprise these above AUR polypeptides is a large variable genera with the potentiality of retaining many activities. Therefore, many functionally unrelated modulators are encompassed within the scope of these claims. The specification discloses only a **single species** for each claimed genus namely, kinase modulators of AUR 1-2, which is insufficient to put one of skill in

the art in possession of the attributes and features of all species within the claimed genus.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (703)308-1235. The examiner can normally be reached on 7:00 a.m to 5:30 p.m. except for Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (703)308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

M. Monshipouri

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER

***